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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/594,685	06/16/2000	Kieran P. J. Murphy	8627/405	2321

7590

03/24/2004

BRINKS HOFER GILSON & LIONE
P.O. Box 10395
Chicago, IL 60610

EXAMINER

ROBERT, EDUARDO C

ART UNIT	PAPER NUMBER
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3732

28

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/594,685

Applicant(s)

MIRPHY, KIERAN P. J. *cn*

Examiner

Eduardo C. Robert

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In view of the Appeal Brief filed on January 15, 2004, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Lazarus, et al.

Lazarus, et al. disclose a kit 10 comprising a first tray 10a of components and a second tray 10b of components. The first and second tray are individually assembled and packaged and are kept sterile until use.

Art Unit: 3732

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vagley (U.S. Patent No. 6,158,437 cited on PTO-892, paper no. 9).

Vagley discloses a method of performing a surgical procedure wherein an instrument support tray is provided having a plurality of surgical instruments positioned thereon (see col. 1, lines 65-67). Vagley further discloses that the tray can be customized to cater to the preference of a specific surgeon during a specific procedure and in such case may also provide additional equipment preferences of the surgeon. All this is directed toward enhanced efficiency in the surgical site and more accurate and prompt delivery of the correct instrument to the surgeon (see col. 5, lines 40-50). Vagley define a surgical procedure as "a procedure performed on a patient by a physician, dentist, veterinarian or other legally authorized health care professional which procedure involves a plurality of hand-held instruments and is at least partially invasive." (see col. 3, lines 5-10). Thus, it would have been obvious to one skill in the art at the time the invention was made to place specific tools, such as local anesthesia, anesthesia aspiration syringe; anesthesia aspiration needle; anesthesia injection needle; liquid monomer; monomer aspiration needle; monomer aspiration syringe; mixing bowl; mixing spatula; polymer powder; opacifier; scalpel; vertebroplasty needle, etc., need in a tray to cater to the preference of a specific surgeon during a specific procedure.

Art Unit: 3732

Claims 1-16, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vagley (U.S. Patent No. 6,158,437 cited on PTO-892, paper no. 9) and Shanley, et al.; Macleod, et al.; Smith, et al.; Arlers; Racz; Jiang, et al.; Singer; Draenert; Haynie; Hertzman, et al.; and Baker are cited as evidence.

Vagley discloses a method of performing a surgical procedure wherein an instrument support tray is provided having a plurality of surgical instruments positioned thereon (see col. 1, lines 65-67). Vagley further discloses that the tray can be customized to cater to the preference of a specific surgeon during a specific procedure and in such case may also provide additional equipment preferences of the surgeon. All this is directed toward enhanced efficiency in the surgical site and more accurate and prompt delivery of the correct instrument to the surgeon (see col. 5, lines 40-50). Vagley define a surgical procedure as "a procedure performed on a patient by a physician, dentist, veterinarian or other legally authorized health care professional which procedure involves a plurality of hand-held instruments and is at least partially invasive." (see col. 3, lines 5-10). Shanley, et al. disclose that kits or tray can include a local anesthesia injection needle 6. Macleod, et al. disclose that kits or tray can include a local anesthesia compound. Smith, et al. disclose a aspiration syringe for fluids (see col. 9, lines 9-11). Arlers discloses another aspiration syringe. Racz discloses an aspiration needle for fluids. Jiang, et al. disclose that liquid monomers can be on a kit or tray. Singer discloses another aspiration needle. Draenert discloses a mixing bowl and polymeric powder. Haynie discloses that a tray or kit can have a mixing spatula. Hertzman, et al. disclose that a tray or kit can include a scalpel. Baker discloses that a tray or kit can include opacifier. Thus, it would have been obvious to one skill in the art at the time the invention was made to place specific tools, such as local anesthesia, anesthesia

Art Unit: 3732

aspiration syringe; anesthesia aspiration needle; anesthesia injection needle; liquid monomer; monomer aspiration needle; monomer aspiration syringe; mixing bowl; mixing spatula; polymer powder; opacifier; scalpel; vertebroplasty needle, etc., need in a tray to cater to the preference of a specific surgeon during a specific procedure.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

In response to applicant's argument that Lazarus et al. do not have a "vertebroplasty injection components", it is noted that Lazarus's tray 10b includes a syringe 36 and needle 38 and they are capable of being used in a spinal surgical procedure, e.g. for injecting anesthesia. Lazarus's tray 10a includes a cannula for injecting and/or aspirating fluid and it is capable of being used in a spinal surgical procedure, e.g. for injecting or aspirating nucleus pulposus. Thus, it is clear that each tray include a injection component and they can perform a function in spinal surgery if one so desire.

In response to applicant's argument that Lazarus et al. do not disclose the functional language "such that said second tray of said vertebral body", it is noted that one of the tray of Lazarus can remain sterile for use in another procedure if the other tray is sufficient for the procedure being performed. Now, that the procedure is not the same as the procedure by applicant, it is noted that the Lazarus kit has the ability to perform the functional language of the claim. Furthermore, it is noted that the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under

Art Unit: 3732

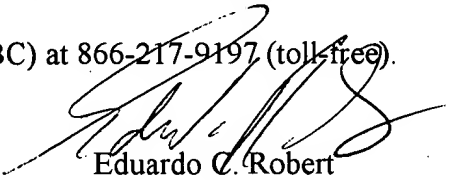
attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). The manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 703-305-7333. The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on 703-308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eduardo C. Robert
Primary Examiner
Art Unit 3732

E.C.R.